

Comparison between stented, stentless and transcatheter aortic valve bioprostheses using 4D flow magnetic resonance imaging

Published: 29-10-2014

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Compare hemodynamic parameters and flow patterns of the stented Mitroflow bioprosthesis, stentless Freedom SOLO bioprosthesis, transcatheter Edwards Sapien bioprosthesis and healthy control subjects, measured with 4D flow MRI.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON44677

Source

ToetsingOnline

Brief title

Aortic valve bioprostheses in 4D flow MR

Condition

- Cardiac valve disorders

Synonym

aortic valve bioprostheses, prosthetic heart valve

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: AMC

Intervention

Keyword: 4D flow, aortic valve, bioprostheses, MRI

Outcome measures

Primary outcome

maximum and average flow velocity, flow pattern and wall shear stress and kinetic energy loss over the aortic valve

Secondary outcome

nvt

Study description

Background summary

When a patient needs an aortic valve replacement there are multiple heart valve prostheses available. All have their pros and cons. De biological aortic valve prosthesis increased tremendously the last decade. The disadvantage of the biological prosthesis is its durability. The valves that represent the most physiological flow will maybe be the most durable ones. Recently, 4D flow MRI sequence has become available to assess flow patterns across heart valves in multiple dimensions over time.

Study objective

Compare hemodynamic parameters and flow patterns of the stented Mitroflow bioprosthesis, stentless Freedom SOLO bioprosthesis, transcatheter Edwards Sapien bioprosthesis and healthy control subjects, measured with 4D flow MRI.

Study design

Pilot study

Study burden and risks

no risks

Scan takes 40 minutes, if possible planned during regular visit in outpatient

clinic

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Scientific

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Adult patients who had an aortic valve replacement with a Mitroflow or SOLO bioprotheses, or a transcatheter aortic valve implantation with an Edwards Sapien.

Exclusion criteria

Multiple valve replacements

Contraindication for MRI (see protocol for specification)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	14-12-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO	
Date:	29-10-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	06-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

4 - Comparison between stented, stentless and transcatheter aortic valve bioprosthesis ... 9-05-2025

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL50502.018.14